

Appl. No. 10/694,130
Atty. Docket No. 6373R2RD2
Amdt. Dated April 19, 2005
Reply to Final Office Action Dated January 21, 2005
Customer Number 27752

REMARKS

Claim 1 is amended to specify that the composition does not contain a synthetic linear polymeric polycarboxylate salt and the limited water content functions to inhibit hydrolysis of the polyphosphate.

Claim 10 is amended to exclude synthetic linear polymeric polycarboxylate salts as "tartar control agents" to be consistent with the amendment to Claim 1. The synthetic linear polymeric polycarboxylate salts have been indicated to be useful as tartar control agents.

It is believed these changes do not involve any introduction of new matter. Consequently, entry of these changes is believed to be in order and is respectfully requested.

Claims 1 to 12 remain pending in the application.

New Matter

It is asserted in the Advisory Action that the claim amendment to exclude a synthetic linear polycarboxylate salt from the composition, stating that the negative limitation is not specifically supported in the Specification as originally filed. Thus, the amendments filed in response to the Final office Action were not entered. It is further indicated that the amendment raises new issues that would require further consideration and/or search.

Applicants respectfully submit that the generic disclosure of optional anticalculus agents provided in the instant application supplies sufficient written description support for excluding synthetic linear polycarboxylate salt, a species within the genus of anticalculus agents. Support for the proposition that claims can be properly amended to exclude a particular species of a genus can be found in § 2173.05(i) in the MPEP which states:

...there is nothing inherently ambiguous or uncertain about a negative limitation. So long as the boundaries of the patent protection sought are set forth definitely, albeit negatively, the claim complies with the requirements of 35 U.S.C. 112, second paragraph.

If alternative elements are positively recited in the specification, they may be explicitly excluded in the claims. See In re Johnson, 558 F.2d 1008, 1019 194 USPQ 187, 196 (CCPA 1977) ("[the] specification, having described the whole, necessarily

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described the part remaining."... Note that a lack of literal basis in the specification for a negative limitation may not be sufficient to establish a prima facie case for lack of descriptive support.

The *Johnson* court held that a disclosure of a genus and examples of representative species is sufficient to support a negative limitation in the claims in the absence of the limitation in the specification.

In *Johnson*, a genus of polyarylene polyethers was originally claimed including a species that include a sulfone linking group and a species that include a carbonyl linking group. The original application was involved in an interference which resulted in an award of priority adverse to the *Johnson* applicants. After the interference ended, the *Johnson* applicants filed an application with claims excluding the subject matter of the lost count. The claims at issue were amended with the proviso that the group linking the aromatic nuclei may not be a divalent sulfone group or a divalent carbonyl group. The species with the sulfone group is the species of the lost count in the interference and the species with a divalent carbonyl group was considered by the applicants as "analogous" or "equivalent" to the species of the lost count. Thus both species were excluded.

The claims with the negative limitation were rejected by the Examiner and the Board under 35 U.S.C. § 102 or 103 over a foreign-filed counterpart of the applicant's original application, with a view that the new claims are not entitled to the original filing date because the presently claimed subject matter is not "described" in the original application as required by the first paragraph of 35 U.S.C. § 112. Thus, the foreign-filed application was considered as available as prior art.

On appeal, the CCPA reversed the rejection of the claims under § 102 or § 103, stating that the invention excluding two species as recited in the claims is "disclosed in the manner provided by the first paragraph of section 112" in the original application and that the claims are entitled to the benefit of the original filing date. Therefore, the cited reference was not available as prior art and the rejection under §102 or §103 was reversed. As stated therein:

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Here, as we hold on the facts of this case, the "written description" in the 1963 specification supported the claims in the absence of the limitation, and that specification, having described the whole, necessarily described the part remaining. The facts of the prosecution are properly presented and relied on, under these circumstances, to indicate that appellants are merely excising the invention of another, to which they are not entitled, and are not creating an "artificial subgenus" or claiming "new matter."

It is respectfully submitted that in accordance with the *Johnson* standard, there is sufficient support for excluding synthetic linear polycarboxylate salt from the present claimed compositions, and that no new matter is introduced with the amendments to the claims with such exclusion.

Claims Rejection Under 35 U.S.C. §103(a)

It is stated in the Office Action that the rejection of Claims 1-12 under 35 USC §103(a) as being unpatentable over Gaffar et al. (US 4,627,977) in view of Crisanti et al. (US 4,902,497) is maintained.

Applicants respectfully traverse the Examiner's rejection of the claims under 35 USC 103(a) and submit that Claims 1-12 as now presented are distinct and unobvious from the cited art.

As now claimed, the present single-phase compositions are distinct from the Gaffar compositions which require the presence of from 0.05% to 3% of a water-soluble alkali metal or ammonium synthetic anionic linear polymeric polycarboxylate salt to inhibit enzymatic hydrolysis of the polyphosphate salt in saliva in the polyphosphate. The present claimed compositions specifically do not contain such synthetic anionic linear polymeric polycarboxylate salt and are formulated with a limited water content to minimize the hydrolysis of the polyphosphate, which would reduce the availability of polyphosphate in the composition.

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There is no disclosure whatsoever in Gaffar relating to the use of stannous as antigingivitis and antiplaque agent. In fact, Gaffar's compositions would only have stannous if stannous fluoride were selected as the fluoride source. There is no disclosure to use a stannous salt to supply stannous ions much less to use a stannous salt other than stannous fluoride or stannous monofluorophosphate as contemplated in the present compositions. There is no specific teaching in Gaffar to limit the water content to no more than 20% to minimize the hydrolysis of the polyphosphate. Indeed, Gaffar exemplifies a dentifrice composition comprising a polyphosphate (Hexaphos), sodium fluoride, and 37.578% water. Gaffar recognizes that polyphosphates are subject to enzymatic hydrolysis and thus teaches to use the combination of fluoride and synthetic linear polycarboxylate to inhibit such hydrolysis.

It is asserted that Gaffar teaches that "other anticalculus agents" may be incorporated in the composition and that it would have been obvious to use a stannous compound such as taught by the secondary reference Crisanti et al. as such "other anticalculus agent" in Gaffar's composition and thus arrive at the present invention. Crisanti indeed teaches the use of stannous compounds such as stannous chloride and stannous gluconate complexed with certain acids or alcohols as anticalculus agents and that the complexed stannous compound provides sustained levels over extended periods of time, and thus improved anticalculus activity.

Applicants respectfully submit that including Crisanti's stannous compounds into Gaffar's composition would still not arrive at the presently claimed compositions. The combination would still require the synthetic linear polymeric polycarboxylate required by Gaffar to inhibit enzymatic hydrolysis of the polyphosphate component. The present claims specifically exclude such synthetic linear polymeric polycarboxylate. Instead, the present compositions are formulated with a limited total water content of not more than 20% to minimize polyphosphate hydrolysis. There is no specific teaching or suggestion in either Gaffar or Crisanti with respect to limiting the water content of the compositions to avoid polyphosphate hydrolysis. Indeed, Gaffar's exemplification of a polyphosphate, Hexaphos, in a composition containing 37.578% added water teaches away from the present claimed

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composition, which contains significantly less water and does not contain Gaffar's synthetic linear polymeric polycarboxylate. Crisanti does not remedy this deficiency. Therefore, the claimed invention is unobvious and the rejection under 35 USC 103(a) should be withdrawn.

CONCLUSION

Applicants have made an earnest effort to place their application in proper form and to distinguish the invention as now claimed from the applied references. In view of the foregoing, reconsideration of this application, entry of the amendments presented, withdrawal of the claims rejection under 35 USC 103(a) and allowance of Claims 1 to 12 are respectfully requested.

The Examiner is respectfully invited to telephone the undersigned representative if he believes an interview might be useful to advance prosecution of this case.

Respectfully submitted,

THE PROCTER & GAMBLE COMPANY

By *Emelyn L. Hiland*
Signature

Emelyn L. Hiland

Typed or Printed Name

Registration No. 41,501

(513) 622-3236

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